Supreme Court, U.S.
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IN THE

# Supreme Court of the United States

OCTOBER TERM, 1993

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RYAN THOMAS, a minor by Roberta Thomas and Ronald C. Thomas, Jr., his natural parents and guardians,
*Petitioner*,

v.

PAUL D. ZUBRITZKY and The Upjohn Company and Merrell Dow Pharmaceuticals, Inc.,
*Respondents*.

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**On Petition for a Writ of Certiorari to the Superior Court of Pennsylvania**

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## PETITION FOR A WRIT OF CERTIORARI

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## QUESTION PRESENTED

Whether, in light of the Due Process Clause of the Fourteenth Amendment of the United States Constitution which provides that an individual has a right to be heard on the merits of his case, state courts may weight evidence to determine the truth of the matter at the summary judgment stage, thereby prematurely granting a summary judgment when a genuine issue as to material questions of fact exist.

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**On Petition for a Writ of Certiorari to the Superior Court of Pennsylvania**

---

## PETITION FOR A WRIT OF CERTIORARI

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Ryan Thomas, a minor by Roberta Thomas and Ronald C. Thomas, Jr., his parents and natural guardians, respectfully petitions for a writ of certiorari to review the judgment of the Superior Court of Pennsylvania in this case.

### OPINIONS BELOW

The opinion of the Superior Court (App., infra, 4a) and the opinion of the Court of Common Pleas (App., infra, 29a) are unreported.

### JURISDICTION

The Superior Court entered its judgment on December 16, 1992. The Supreme Court of Pennsylvania entered its denial of the Petition For Allowance of Appeal and Cross Petition on February 14, 1994 (App., infra, 1)

The jurisdiction of this Court is invoked under 28 U.S.C. § 1257(a).

## STATUTORY PROVISION INVOLVED

The Pennsylvania rules of civil procedure, Pa. R.C.P. 1035(b) provides, in relevant part, that a summary judgment is properly granted only where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law."

## STATEMENT OF THE CASE

In July 1989, petitioner, Ryan Thomas, through his parents, Roberta and Ronald Thomas, sued Paul D. Zubritzky, M.D. alleging that Dr. Zubritzky was negligent in failing to take an adequate family history from Mrs. Thomas, in failing to diagnose Mrs. Thomas' pregnancy with the petitioner, in failing to warn petitioner's parents of alleged dangers of fetal exposure to Provera sold by The Upjohn Co. ("Upjohn") and Clomid sold by Merrell Dow Pharmaceuticals ("Merrell"), and in failing to conduct appropriate prenatal testing, which negligence allegedly led to Ryan Thomas being born with various problems, including thoracic myelomeningocele [1], more commonly known as spina bifida [2], Arnold-Chiari malfor-

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[1] A myelomeningocele is a sac-like protrusion of the meninges (the three layers of membrane enclosing the brain and spinal cord) through an opening in the wall of the spinal canal which contains nerves and cerebrospinal fluid. Schmidt's Attorneys' Dictionary of Medicine, Volume 2 at M-78 and M-207 (1988) and Volume 3 at 58 (1990 Supp.).

[2] Spina bifida is a congenital defect occurring during the embryonic development of the spine which leaves the wall of the spinal canal open at some point such that the meninges covering the spinal cord protrude therefrom and form a sac or hernia containing nerves and/or cerebrospinal fluid. Schmidt's Attorneys' Dictionary of Medicine, Volume 3 at S168-S169 (1989).

mation,[3] and hydrocephalus.[4] (R. 8a-19a.)[5]

Dr. Zubritzky then joined The Upjohn Company and Merrell Dow Pharmaceuticals as additional defendant. Dr. Zubritzky averred that neither Provera nor Clomid caused the plaintiff's injuries, but then alleged that, if causation were to be established, the manufacturers' warnings concerning these prescription drugs were inadequate. (R. 22a-39a.)

**A. Case History—Factual Background.**

Roberta and Ronald Thomas desired to have a child and sought fertility treatment from Respondent Paul D. Zubritzky, M.D. because of an irregular or non-existent menstrual cycle. Treatment commenced in the early months of 1983.

Dr. Zubritzky prescribed for Mrs. Thomas both Provera, a drug manufactured by Upjohn for regulation of menstrual periods, and Clomid, a drug manufactured by Merrell to increase chances of conceiving. Mrs. Thomas took both drugs at the beginning of each of several months according to Dr. Zubritzky's instructions. (R. 318a-334a.)

In 1983, Provera was accompanied by a warning against its use during pregnancy. This warning appeared

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[3] A defect of this type is a developmental deformity characterized by smallness of the medulla oblongata and pons regions of the brain and the protrusion of these structures and other parts of the brain through the foramen magnum (the large opening in the back of the skull). Schmidt's Attorneys' Dictionary of Medicine, Volume 1 at A307 (1985). As part of this condition, the protruding portions of the brain and the meninges may also descend into the spinal canal. *Id.*

[4] Hydrocephalus is a condition in which an abnormal amount of cerebrospinal fluid accumulates within the cranial cavity. Schmidt's Attorneys' Dictionary of Medicine, Volume 2 at H-132 (1987).

[5] References in this form are to the reproduced record filed by the Petitioner (appellant) in the Superior Court.

in the package insert and in the Physician's Desk Reference, a compilation of package inserts furnished free of charge to physicians on an annual basis. The warning also appeared in all Provera advertisements published in medical journals. The warning stated, in part:

> WARNING
>
> THE USE OF PROGESTATIONAL AGENTS DURING THE FIRST FOUR MONTHS OF PREGNANCY IS NOT RECOMMENDED. . . .
>
> There is evidence of potential harm to the fetus when such drugs are given during the first four months of pregnancy. . . .
>
> If the patient is exposed to Provera (medroxyprogesterone acetate) during the first four months of pregnancy or if she becomes pregnant while taking this drug, she should be apprised of the potential risks to the fetus. (R. 335a-341a)

Dr. Zubritzky was apparently aware of the Provera warning and knew that a new cycle of Provera should not be started until a negative pregnancy test has been obtained. Blood serum pregnancy tests were done on the second, third and fourth cycles of treatment to determine if Mrs. Thomas was pregnant. (R. 271a-274a, 318a-334a.)

After completion of the fourth cycle of these drugs, Mrs. Thomas was examined by Dr. Zubritzky in July, 1983 at which time she informed him that she thought or felt herself to be pregnant. On this occasion, Dr. Zubritzky performed only a urine pregnancy test in his office which he interpreted as yielding a negative result. Mrs. Thomas was advised to continue taking the Clomid and Provera and she did as instructed. Mrs. Thomas performed a home pregnancy test on July 20, 1983 which revealed that she was pregnant. Her pregnancy was later confirmed by a subsequent test conducted by Dr. Zubritzky, Mrs. Thomas did not take any further Clomid or

Provera following the diagnosis of her pregnancy by Dr. Zubritzky. (R. 318a-334a.)

On February 24, 1984, Mrs. Thomas gave birth to Ryan Thomas. Ryan was born with, among other things, a thoracic myelomeningocele, which is more commonly known as spina bifida. Ryan was further diagnosed as having an Arnold-Chiari malformation and hydrocephalus. Surgery was performed on Ryan to correct, insofar as possible, his serious birth defects. However, Ryan has never been able to use his legs due to his condition.

**B. Proceedings Below—Summary Judgment Record.**

Mr. and Mrs. Thomas believe that Ryan's birth defects were causally related to Mrs. Thomas' ingestion of Clomid and/or Provera during the early stages of her pregnancy. As a result, Petitioner initially commenced suit against Dr. Zubritzky in 1985. This action was voluntarily discontinued by Petitioner on March 3, 1988. Petitioner was represented by different counsel in this action.

Petitioner thereafter instituted the present action against Dr. Zubritzky. Dr. Zubritzky joined Merrell and Upjohn as additional defendants. Both additional Defendants moved for summary judgment primarily on the issue of causation, contending that, as a matter of law, their drugs could not have caused Ryan's birth defects.

Additional Defendant, Upjohn also moved for summary judgment on the grounds as a matter of law that warnings on their products were adequate and that they cannot be held to be liable.

These motions were granted by the trial court and summary judgment was entered on September 19, 1991. Following the entry of summary judgment, Dr. Zubritzky filed a motion for clarification of the trial court's orders. This motion was granted and on September 30, 1991, Judge McLean clarified his order granting Upjohn's sum-

mary judgment motion to include, as a separate and distinct basis for the summary judgment, that the warning Upjohn had provided with Provera advising that it not be used during pregnancy "was adequate as a matter of law" and, thus, that Provera was not defective. Petitioner filed a motion for reconsideration which was denied.

Original Defendant, Dr. Zubritzky moved and was granted summary judgment on October 17, 1991 after the additional Defendants were granted summary judgment in that he could not be held liable if in fact the drugs, as a matter of law, did not cause the Petitioner's injuries.

Petitioner initially filed an appeal from the order entered September 19, 1991, granting Upjohn's motion for summary judgment; this appeal is docketed at No. 01821 Pittsburgh 1991, which clarified the prior order. Dr. Zubritzky's appeal is docketed at No. 01868 Pittsburgh 1991. Petitioner also instituted an appeal from the order of clarification, entered September 30, 1991; this appeal is docketed at No. 01943 Pittsburgh 1991. Finally, Petitioner appealed from the order entered on October 17, 1991 which granted Dr. Zubritzky's motion for summary judgment; this appeal is docketed at No. 01942 Pittsburgh 1991. All of these appeals were consolidated for review by order of the Superior Court entered on February 7, 1992. None of the parties instituted an appeal from the September 19, 1991 order granting summary judgment in favor of Merrell.

On December 16, 1992, the Superior Court upheld the judgment of the Court of Common Pleas in granting the entry of summary judgment in favor of original Defendant Paul D. Zubritzky and additional Defendant Upjohn. Superior Court agreed with the lower court both that petitioner had failed to show that there was any triable issue with respect to whether Provera could cause the injuries complained of and that, as a matter of law, Upjohn's package insert was sufficient to shield it from liability.

In moving for a summary judgment on the issue of causation, both additional Defendants provided credible evidence in support of their contentions. In responding to the motion for summary judgment, the Petitioner submitted the expert reports of a number of credible physicians. The record indicates that the Court of Common Pleas either disregarded or discounted the Petitioner's evidence or decided the summary judgment issued by weighing the evidence to determine the truth of the matter.

In his Memorandum Opinion (App. infra, 29a) upholdsummary judgment (R. 498a-502a), the Honorable James H. McLean appeared to reject the conclusions in the expert reports submitted by Petitioner finding them "highly conjectural" and "plainly maverick in nature". He went on to state that he was *contrasting* Petitioner's proof with the "highly credible and substantial evidence offered by the Defendants" (R. 498a-502a). There is no basis or grounds for this determination regarding the weight of the evidence and it should not have been a determination for the trial court to make while ruling on summary judgment motions. It is not the trial court's purpose to determine the truth of the matter in ruling on motions for summary judgment. The trial court's task must be confined to deciding whether material questions of fact exist to submit to a fact finder.

The Superior Court affirmed the trial court's decision by improperly weighing the evidence. In its Memorandum Opinion (App. infra, 4a, the Superior Court recognized and accepted Dr. Goldman's report, citing the opinions set forth (App. infra 16a-18a). The Court found Dr. Goldman's opinions to be inadequate in light of the Defendant's expert opinions (App. infra 18a). The Court clearly weighed the evidence to reach its decision, contrary to the established rule of law.

The adequacy of the Upjohn warning also presents a questions of fact to be determined in light of Petitioner's

allegations. Under the law of Pennsylvania, the adequacy of a warning accompanying a prescription drug presents a questions of fact for the jury. *Incollingo v. Ewing*, 444 Pa. 263, 282 A.2d 206, 219-220 (1971).

The Superior Court once again incorrectly weighed the evidence on this issue, stating "(W)e will evaluate the adequacy of the warning in accordance with these decisions." (App. infra 20a-21a). The Court stated it was rejecting Petitioner's contentions on this issue in finding the warning adequate.

On January 15, 1993, Petitioner filed a Petition for Allowance of Appeal to the Supreme Court of Pennsylvania stating that "The Superior Court had decided a question of substance in a manner not in accord with and contrary to applicable decisions of the Supreme Court of Pennsylvania and the Supreme Court of the United States," and in so doing presented the federal question (Petitioner's Petition for Allowance of Appeal p.5.) Respondent, Paul D. Zubritzky, M.D. filed a Cross-Petition for Allowance of Appeal. The Supreme Court of Pennsylvania denied the Petition and Cross-Petition on February 14, 1994.

## REASONS FOR GRANTING THE WRIT

The decision of the Superior Court of Pennsylvania in affirming the trial court's decision in granting a summary judgment is erroneous in that evidence was weighed to determine the truth of the matter and not whether a genuine issue of material fact existed. The decision violates the Due Process Clause of the Fourteenth Amendment and conflicts with federal court decisions on summary judgments. This case is an opportunity to provide guidelines on an important and fundamental individual right.

### I. THE DECISION OF THE SUPERIOR COURT OF PENNSYLVANIA IS ERRONEOUS.

This Court has ruled consistently that summary judgments will not lie if the dispute about a material fact is "genuine," that is, if the evidence is such that a reasonable jury could return a verdict for the non-moving party. At the summary judgment stage, the trial judge's function is not himself to weight the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 24, 106 S.Ct. 2505 (1986).

Both the Superior Court and trial court in erroneously disregarding Pennsylvania law (which parallels federal law) have gone beyond the summary judgment stage and weighed the evidence to determine, not whether there is a genuine issue for trial, but to determine the truth of the matter. This is a clear abuse of discretion that cannot be allowed to stand in the face of this Court's rulings and the Constitution of the United States.

In *Ambrosini v. Labarraque*, 966 F.2d 1464, (D.C. Cir. 1992), a case strikingly similar to the case at hand, the U.S. Court of Appeals for the District of Columbia Circuit reversed the district court's grant of a summary judgment as premature. One of the Plaintiff's expert witnesses was Dr. Allen S. Goldman, the same expert witness for the Petitioner Ryan Thomas in the present case.

In *Ambrosini*, the district court granted a summary judgment in favor of the defendant, The Upjohn Company and Dr. Jorge Labarraque holding that the Ambrosini's had failed to present specific, admissible scientific evidence sufficient to create a genuine issue of material fact on the issue whether the drug Depo-Provera [6] caused the birth defects suffered by Teresa Ambrosini. *Id.* at 1464.

Dr. Goldman's affidavit in *Ambrosini* and his expert report in the Petitioner's case are also strikingly similar. In the *Ambrosini* affidavit, Dr. Goldman stated, in relevant part, that:

> "I am familiar with the available scientific and epidemiological data concerning progestin and progesterone agents including the product manufactured by the defendant Upjohn Company known as Depo-Provera, and it is my opinion within a reasonable degree of medical and scientific certainty that Depo-Provera does cause severe and disfiguring birth defects of the type that is suffered by Teresa Ambrosini. It is further my opinion that within a reasonable degree of medical certainty Teresa Ambrosini's birth defects were a result of the investion of Depo-Provera. *Id.* at 1466.

**A. Petitioner's Expert Reports.**

Dr. Goldman's January 2, 1986 expert report (App. infra 34a) in the Petitioner's case, stated, in relevant parts, that:

> "I have set forth my opinions reached as a result of an evaluation of events surrounding the birth of Ryan C. Thomas, born of February 26, 1984. In doing so. I have reviewed the following documents and materials: (a) the hospital records from Ohio Valley General Hospital pertaining to the birth of Ryan Thomas; (b) the laboratory records from Ohio Valley Hospital for blood pregnancy tests; (c) the

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[6] Depo-Provera is a longer acting form of Provera but consists of the same chemical entity, progesterone. Facts and Comparisons at 665 (1994).

in-patient records of Ryan Thomas from Children's Hospital of Pittsburgh from February 26, 1984 through March 30, 1984; (d) a receipt from prescriptions filled by Dr. Zubritzky for Roberta Thomas for the period from January 1, 1983 through December 31, 1983; (e) the 1939 records from The Valley Hospital and (f) a case history. . . .

Mrs. Thomas took the Provera July 5, 1983 through July 14, 1983. On July 18, 1983 she began spotting, the next day she obtain a home pregnancy test and found it was positive. She was examined by Dr. Zubritzky on July 28, 1983 and was thought to be about eight (8) weeks size on pelvic examination. On October 5, 1983 she had a sonogram which gave the gestational age of eighteen (18) weeks, or a conception date on or about June 2, 1983.

It is my considered opinion that the thoracomyelomeningocele was a direct result of the progestins and possible estrogens to which the fetus was exposed in the earlier stages of Roberta Thomas' pregnancy. Provera is a progestin and Clomid as an estrogen.

In conclusion, it is my considered opinion that the fetal exposure to Provera and possibly Clomid caused the neural tube defect from which this child suffers." (R. 434a-435a).

Dr. Goldman's affidavit in *Ambrosini*, as in the present case, did not, however, explain in detail the basis for his conclusion nor did it specifically state which studies, report, or articles he relied on. *Id.* at 1466.

It is clear, however, that Dr. Goldman set forth specific facts by a review of the relevant medical records of Mrs. Thomas and Ryan Thomas that Provera and Clomid caused Ryan Thomas' birth defects. There was a sufficient factual basis to defeat a summary judgment at this point.

The Pennsylvania Rules of Civil Procedure Pa. R.C.P. Rule 1035(d) closely follow Rule 56(e) of the Federal Rules of Civil Procedure governing *Ambrosini*.

Rule 1035(d) states that:

> When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of his pleadings, but his response, by affidavits or as otherwise provided in this rule, must set forth *specific facts showing that there is a genuine issue for trial.* If he (or she) does not respond, summary judgment, if appropriate, shall be entered against him. Pa. R.C.P. Rule 1035(d). (*Marks v. Tasman*, 527 Pa. 132, 589 A.2d 205 (1991).

Rule 56(e) states that, in order to defeat a well-supported motion for summary judgment, an affidavit in response to the motion "must set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e).

Upjohn argues, and the trial judge and Superior Court would agree, that because the report of Dr. Goldman did not explain in detail the reasoning behind his opinion, it is insufficient under Rule 1035(d) to defeat a motion for summary judgment. (App. infra 18a.)

In another report by Dr. Goldman dated November 13, 1985, (App. infra 37a) scientific data concerning progestin is in fact cited. This report stated, in relevant part, that:

> "I have carefully reviewed all the materials which you have sent me and have done a preliminary literature search concern the possibility that the child's multiple birth defects were due to the combination of the mother's exposure to Clomid and Provera.
>
> Concerning the thoraco-myelomenicgocle one of the earliest reports in which the malformations of other organs was attributed to the use of exogenous progestins was that of Uhlig (1). He observed three deformed infants with central nervous system defects (like the present case), club foot, and limb reduction defects. . . . The incidence of CNS malformations has fallen in the United States (14), Ireland

(15), and England (16) during the years after these progestins were reported to be teratogenic.

Thus, there is evidence of association of CNS defects with exposure in early pregnancy to both progestins ad estrogens, which the present case is an example, Provera being a progestin and Clomid being an estrogen.

There are several reports however, indicating that there is little to no teratogenic risk (see enclosed copy). In my opinion, the weight of the evidence is in favor of the teratogenicity of the exposure to these two agents and the time of exposure is in the right period." (R. 436a-437a).

In total, the report provides 16 citations indicating evidence of teratogenicity for the two drugs taken by Mrs. Thomas.

Finally, Dr. Goldman states in a follow up report dated June 16, 1986 (App. infra 39a) that Ryan Thomas' birth defects can be attributed to the exposure of his mother, Mrs. Thomas, to Provera and Clomid. That report stated, in relevant part, that:

"Based upon the above, it is my opinion, on the basis of a reasonable degree of medical certainty, that the early conceptus was exposed to Clomid.

The fact that Mrs. Robert M. Thomas was given 150mg/day instead of 100mg/day of Clomid for five (5) days would result in a higher concentration of this drug in her system for a longer period of time.

Thus, it is likely that the defects occurring in Ryan can be attributed to the increased risk of spina bifida due to exposure to these drugs." (R. 438a).

In yet another expert report submitted by the Petitioner (App. infra 41a) in a Motion for Reconsideration, Dr. David Abramson stated, in relevant part, that:

"I have now had a chance to carefully review all of the records that you forwarded for the pregnancy,

> birth, pediatric care, and follow-up care of Ryan Thomas. I have also reviewed the appropriate literature but I have not had the opportunity to examine this child. Based on my examination, I have the following understanding and hold the following opinions in this case. . . .
>
> The pregnancy in question was not diagnosed until after Provera had been given during the first trimester. Because compliance with the admonition against Provera's use in pregnancy has been so good, too few women have been exposed in recent time to draw definitive conclusions about the type of malformations that may result. Certainly, dymorphogensis is known to occur in the presence of a host of nonphysiologic fetal environments. . . .
>
> It is my very strong opinion that standard avoidance of fetal Provera exposure would probably have prevented this child's Arnold-Chiari II malformation." (R. 485a).

The trial judge, however, failed to view the evidence as setting forth a specific fact or facts, but instead clearly weighed the evidence and concluded that the drugs taken by Mrs. Thomas did not cause Ryan Thomas' birth defects. (App. infra 33a.)

The Superior Court cited *Brecher v. Cutler*, 396 Pa. Super. 211, 578 A.2d 481 (1990) which stated that: "Bold unsupported assertions of conclusory accusations cannot create genuine issued of material fact."

The court is in error applying *Brecher* to the Petitioner's case because in *Brecher*, no evidence existed in the medical literature to support *Brecher*'s claim so it could not be included in any affidavits. *Id.* at 482. In Ryan Thomas' case, Dr. Goldman based his opinion on published medical information and his experience as a practitioner and as a specialist in pediatrics, craniofacialanomlies and genetics.

To uphold a summary judgment, there must not only be an absence of genuine factual issues, *but also* an entitlement to judgment as a matter of law. The trial court must examine the record in a light most favorable to the non-moving party and accept as true all well-pleaded facts in the non-moving party's pleadings. *Green v. K & K Insurance Co.*, 389 Pa.Super. 73, 566 A.2d 622 (1989).

The trial court and Superior Court do a grave injustice to Ryan Thomas by characterizing his expert reports as nothing more than conclusory opinions. (App. infra 18a-19a.)

Like any other non-moving party that will bear the burden of proof at trial, Ryan Thomas is entitled to have the credibility of his evidence assumed, his version of all that is in dispute accepted, and all conflicts in it resolved favorably to him. He is also entitled to the most-favorable of all possible inferences from it drawn in his behalf. See *Charbonnages de France v. Smith*, 597 F.2d 406 (4th Cir. 1979).

As the Pennsylvania Supreme court has stated "An entry of summary judgment may be granted only in cases where the right is clear and free from doubt." *Marks* supra at 589 A.2d 205, 206.

**B. The Court Must Look at the Whole Record.**

Rule 1035(b) of the Pennsylvania rules of Civil Procedure states that:

> Summary judgment is properly granted where "the pleadings, depositions, answers to interrogatories, and admission on file, together with the affidavits, if any, show that there is no genuine issues as to any material fact and that the moving party is entitled to a judgment as a matter of law." Pa. R.C.P. Rule 1035(b).

Thus, the court must look at the whole record to determine if there is a genuine issue of material fact for trial. This Court has stated clearly that the record must

be taken as a whole to determine if there is a genuine issue for trial. *First National Bank of Arizona v. Cities Service Co.*, 391 U.S. 253, 289 (1968).

The Superior Court erred when it failed to consider the entire record of the Petitioner's case. The Superior Court only considered the January 2, 1986 report from Dr. Goldman and wrongly excluded his reports of November 13, 1985 and June 16, 1986. (App. infra 14a)

These reports were part of the Petitioner's Answer to Respondent Upjohn's First Set of Interrogatories and were, of course, known to the Respondents. (R. 71a and 96a).

It is also abundantly clear that the trial court considered all of the expert reports by Dr. Goldman when the court mischaracterized the reports. In its opinion, the trial court refers to the aforementioned reports, including Dr. Abramson's reports as follows:

> "This proof consists of a series of letters from physicians flatly stating a correlation between these drugs and neural tube defects and therefore attributing Ryan's problems to that source." (App. infra 33a)

Although the trial court mischaracterized these expert reports and abused it's discretion by weighing the evidence at the summary judgment stage (discussed *infra*), the record clearly shows that the Petitioner's expert reports were accepted and reviewed by the trial court and cannot be disregard by the Superior Court.

Indeed, the Superior Court of Pennsylvania itself has stated that the purpose of Rule 1035(d) is to require that the opposing party disclose the facts of his claim or defense. *Samarin v. Gap Corp.*, 571 A.2d 398 (Pa. Super. 1989), *Roland v. Kranco, Inc.*, 355 Pa.Super. 493, 513 A.2d 1029 (1986). This requirement has surely been met in viewing the entirety of pleadings, depositions, answers to interrogatories, admission and affidavits. The

court cannot use Rule 1035(d) to shift or increase the burden of proof to the non-moving party in a motion for summary judgment. In fact, this Court has stated that:

> "[on] summary judgment the inferences to be drawn from the underlying facts . . . must be viewed in the light most favorable to the party opposing the motion." *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962).

For the Superior Court to do so is a grave injustice and a clear abuse of discretion.

In their Reply Brief in Support of Motion For Summary Judgment to the trial court, the respondents rely on the case captioned *Theresa Ambrosini v. Richardson-Merrell* as being directly on point (and Petitioner agrees) where the same Dr. Goldman's affidavits were found by the U.S. District Court for the District of Columbia to be insufficient, as a matter of law, to survive defendant's summary judgment motion because the affidavits failed to set forth the basis of and foundation for the expert opinions.

On appeal, however, the United States Court of Appeal for the District of Columbia reversed the lower court finding that Dr. Goldman's affidavit set forth a specific fact that was enough to defeat Upjohn's Motion for Summary Judgment and that the district court's grant of summary judgment was premature. See *Ambrosini supra,* at 1470.

The Appeals Court went on to say that when a court denies the right to have a jury decide a disputed issue, especially one of a scientific nature, its reasons for doing so must be strong, (expert opinion based on sound scientific methodology present "a classic battle of the experts, a battle in which the jury must decide the victor"). *Id.* at 1469. Even putting aside Dr. Goldman's other reports, his report of January 2, 1986, indicates he reviewed and considered pertinent documents and records and it established a genuine issue of facts as to whether the two

drugs caused Ryan Thomas' birth defects. It is established common medical knowledge that the most critical period for cogenital birth defects is the first month of pregnancy.[7] Excluding Dr. Goldman's other letters should not be fatal to Petitioner's defeating the Motion for Summary Judgment.

Courts cannot and must not deprive individuals of their fundamental rights under the Constitution and due process by weighing the evidence and determining the truth of the matter at the summary judgment stage.

As stated by this Court in *Anderson v. Liberty Lobby, Inc.*:

> "It is clear enough from our recent cases that at the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986).

The Court should grant Ryan Thomas' petition and correct the Superior Court's error.

## II. THE DECISION OF THE SUPERIOR COURT OF PENNSYLVANIA VIOLATES THE DUE PROCESS CLAUSE OF THE FOURTEENTH AMENDMENT OF THE UNITED STATES CONSTITUTION AND CONFLICTS WITH FEDERAL COURTS.

This Court has referred to "the right to be heard" as "one of the most fundamental requisites of due process." *Schroeder v. New York City*, 371 U.S. 208, 83 S.Ct. 279 (1962).

The practical effect of the decision of the Superior Court of Pennsylavnia in affirming the summary judgment of the trial court is to deprive the Petitioner of his Fourteenth Amendment right by affording the Petitioner no opportunity to be heard. By denying the Petitioner,

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[7] D. M. Davies, Textbook of Adverse Drug Reactions p. 73, 1981.

Ryan Thomas, of the only remedy available, the judgment deprives Ryan Thomas of his rights under due process and closes foreover his right to be heard.

It is one thing to have to live with devastating birth defects, but it is another, which is far more disheartening, to have to live with them with the knowledge that you could not be heard and present your beliefs.

There is a right to be heard on the merits, to have one's day in court. This Court has stated that:

> "due process requires, at a minimum, that absent a countervailing state interest of overriding significance, persons forced to settle their claims of right and duty through the judicial process must be given a meaningful opportunity to be heard." The notice and hearing, says the Court, must be "appropriate to the nature of the case." *Boddie v. Connecticut*, 401 U.S. 371, 91 S.Ct. 780 (1971).

Thus, weighing the evidence to determine the truth of the matter at the summary judgment stage, especially in a complex medical case such as this where expert testimony is absolutely crucial to establish the truth of the matter, is not merely inappropriate but an unjust deprivation of due process rights. Ryan Thomas has been deprived by the state court of his fundamental right to be heard granted by the Constitution. This right to present evidence is essential to the fair hearing required by the due process clause. *Jenkins v. McKeithen*, 395 U.S. 411, 89 S.Ct. 1843, reh den 396 U.S. 869, 90 S.Ct. 35 (1969).

The Constitution also guarantees the Petitioner the right of confrontation. The right to confront and challenge adverse witness. This Court has said,

> "In almost every setting where important decisions turn on questions of fact, due process requires an opportunity to confront and cross-examine adverse witnesses." *Goldberg v. Kelly*, 397 U.S. 254, 90 S.Ct. 1011 (1970).

The due process to a hearing on the merits applies equally to both sides. It also encompasses not only the right to present evidence, but the opportunity to know the claims of the opposing party. *Morgan v. United States*, 304 U.S. 1, 58 S.Ct. 887 (1938). Yes, Upjohn and Dr. Zubritzky have the same rights as Ryan Thomas. The records show that all parties knew the claims of the other parties. The record shows that all parties are entitled to their day in court and a fair and just hearing on the merits.

But to allow a premature summary judgment to stand, where the evidence has been weighed not to determine if a genuine issue exists, but to determine the truth of the matter, makes this Constitutional right barren of meaning. It stands as an empty right for Ryan Thomas, void of substance. It stands crushed by unfairness in the weighing of evidence. "The Fourteenth Amendment forbids fundamental unfairness in the use of evidence, whether true or false" *Blackburn v. Alabama*, 361 U.S. 199, 80 S.Ct. 274 (1960).

In matters where fundamental rights that are guaranteed by the Constitution are involved, judicial self-restraint must be present and maintained. Judges must not substitute their judgment for that of a jury or judge prematurely on the merits of a case. Above all, fundamental rights such as due process must be safeguarded.

The Superior Court and trial court's decision in this case leaves the law in confusion and subject to misinterpretation. Since both the Pennsylvania and Federal rules on summary judgment are virtually identical, a case litigated in federal court will have a different outcome than in a Pennsylvania State Court based on the Appeal Court's decision in *Ambrosini* (supra) that found Dr. Goldman's expert affidavits sufficient to defeat a motion for summary judgment. Thus, future cases may turn on the fortuity of which court, state or federal, or perhaps even which judge, received the case.

In other cases similar to the Petitioner's, appellate courts have reversed summary judgments that were based

on the exclusion of experts' affidavits because of the mistaken belief that they failed to contain specific facts. *M & M Medical Supplies and Service, Inc. v. Pleasant Valley Hospital, et al.*, 981 F.2d 160 (4th Cir. 1992). In *Bulthuis v. Rexall Corp.*, 789 F.2d 1315 (9th Cir. 1985) the court drew a distinction between a wholly conclusory affidavit and an affidavit stating facts but lacking detail. See also *Monks v. General Electric Co.*, 919 F.2d 1189 (6th Cir. 1990) and *Ambrosini* supra.

Cases will continue to be erroneously decided, even in other jurisdictions as different standards are applied to summary judgments, further depriving individuals of their rights under due process. A decision by this Court can resolve this conflict.

Accordingly, in light of the error by the Superior Court and trial court and the violation of the Petitioner Ryan Thomas' rights under the due process clause, the court should grant the petition.

## III. THE QUESTION PRESENTED IS IMPORTANT TO ONE'S INDIVIDUAL RIGHTS AND TO WHAT OUR SOCIETY CONSIDERS WRONG AND UNFAIR.

Justice Frankfurter, who contributed greatly to the definition and expansion of procedural due process, stated in 1950: "the Due Process Clause embodies a system of rights based on moral principles so deeply embedded in the traditions and feelings of our people as to be deemed fundamental to a civilized society as conceived by our whole history." *Solesbee v. Balkcom*, 339 U.S. 9, 70 S.Ct. 457 (dissenting), reh den 339 U.S. 926, 70 S.Ct. 618 (1950). *Leland v. Oregon*, 343 U.S. 790, 72 S.Ct. 1002 reh den 344 U.S. 848, 73 S.Ct. 4 (1952).

On other occasions, this Court has stressed the role of moral conscience in defining due process of law. *Snyder v. Massachusetts*, 291 U.S. 97, 54 S.Ct. 330 (1934). *Malloy v. Hogan*, 378 U.S. 1, 84 S.Ct. 1489.

No procedure or decision that violates due process can be allowed to stand because it places a cloud over an individual's Constitutional rights. In this case, where Peti-

tioner asserts that he has been deprived of a Constitutional right by a state court, a review is required. If a practice or action offends some fundamental principal of justice that is so deeply rooted in the tradition and conscience of our people as is due process and the right to be heard on the merits, it clearly must be examined. See *Leland* supra.

This Court has stated:

> "In a case where it is asserted that a person has been deprived by a state court of a fundamental right secured by the Constitution, an independent examination of the facts by this Court is often required to be made." *Craig v. Harney*, 331 U.S. 367, 67 S.Ct. 1249 (1947).

Without an examination by this Court, cases may continue to be erroneously decided and the fundamental right of an individual to be heard on the merits by a court of his peers will exist not only with a conflict between state and federal law, but under a cloud of injustice to the moral conscience of our society. Therefore, the Court should grant this petition and consider reversing and remanding this case for further proceedings.

## CONCLUSION

For the reasons stated above, Petitioner Ryan Thomas urges that his petition be granted, and that the judgment below be reversed and remanded for a trial on the merits.

Respectfully submitted,

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## APPENDIX A

## THE SUPREME COURT OF PENNSYLVANIA
## WESTERN DISTRICT

CHARLES W. JOHNS, ESQUIRE
Prothonotary
IRMA T. GARDNER
Deputy Prothonotary

801 City-County Building
Pittsburgh, Pa.
15219-2463
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February 15, 1994

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In Re: Ryan Thomas, a minor, by Roberta Thomas and Ronald C. Thomas, Jr., his natural parents and guardians, Petitioners v. Paul D. Zubritzky, Cross-Petitioner v. The Upjohn Company and Merrell Dow Pharmaceuticals, Inc. No. 0013 W. D. Allocatur Docket 1993

Dear Ms. Zhukas and Mr. Jordan:

The Court has entered the following Order on your Petition for Allowance of Appeal and Cross-Petition for Allowance of Appeal filed in the above-captioned matter:

"PER CURIAM:

AND NOW, this 14th day of February, 1994, the Petition for Allowance of Appeal and the Cross-Petition are denied.

Mr. Justice Frank J. Montemuro is sitting by designation as Senior Justice pursuant to Judicial Assignment Docket No. 94 R1800, due to the unavailability of Mr. Justice Rolf Larsen, see No. 127 Judicial Administration Docket No. 1, filed October 28, 1993."

Very truly yours,

/s/ Irma T. Gardner
Deputy Prothonotary

ITG:llb

cc: John J. Repcheck, Esquire
Margaret S. Woodruff, Esquire
David M. Covey, Esquire
Ruthe Nepf Nunez, Esquire
Kathryn Christ, Esquire
Hon. James H. McLean

**APPENDIX B**

SUPERIOR COURT OF PENNSYLVANIA
PITTSBURGH DISTRICT

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No. 1821 Pittsburgh, 1991
No. 1868 Pittsburgh, 1991
No. 1942 Pittsburgh, 1991
No. 1943 Pittsburgh, 1991

RYAN THOMAS, A MINOR BY ROBERTA THOMAS,
AND RONALD C. THOMAS, JR.,
HIS NATURAL PARENTS AND GUARDIANS
*Appellants at 1821, 1942,*
*1943 PGH 91*

-VS-

PAUL D. ZUBRITZKY
*Appellant at 1868 PGH, 1991*

-VS-

THE UPJOHN COMPANY AND
MERRELL DOW PHARMACEUTICALS, INC.,

---

JUDGMENT

ON CONSIDERATION WHEREOF, it is now here ordered and adjudged by this Court that the judgment of the Court of Common Pleas of Allegheny County be, and the same is hereby affirmed.

BY THE COURT:

/s/ [Illegible]
Deputy Prothonotary

DATED: December 16, 1992

**APPENDIX C**

J. A37011/92

IN THE SUPERIOR COURT OF PENNSYLVANIA
PITTSBURGH OFFICE

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No. 01821 Pittsburgh, 1991
No. 01942 Pittsburgh, 1991
No. 01943 Pittsburgh, 1991

RYAN THOMAS, A MINOR BY ROBERTA THOMAS,
AND RONALD C. THOMAS, JR.,
HIS NATURAL PARENTS AND GUARDIANS,
*Appellants*

v.

PAUL D. ZUBRITSKY

v.

THE UPJOHN COMPANY AND
MERRELL DOW PHARMACEUTICALS, INC.

---

No. 01868 Pittsburgh, 1991

RYAN THOMAS, A MINOR BY ROBERTA THOMAS,
AND RONALD C. THOMAS, JR.,
HIS NATURAL PARENTS AND GUARDIANS,

v.

PAUL D. ZUBRITSKY,
*Appellant*

v.

THE UPJOHN COMPANY AND
MERRELL DOW PHARMACEUTICALS, INC.

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Appeals from the Orders of the Court of Common Pleas,
Allegheny County, Civil Division,
at No. G.D. 89-12398

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BEFORE: DEL SOLE, KELLY and BROSKY, JJ.

MEMORANDUM:

FILED: December 16, 1992

These consolidated appeals are from the various orders of the lower court directing and clarifying the entry of summary judgment in favor of the original defendant, Dr. Zubritzky,[1] and the additional defendants, Upjohn Company and Merrell-Dow Pharmaceuticals, Inc.[2] Appellants, Ryan Thomas and his parents Roberta and Ronald Thomas, present the following issues for review: (1) whether appellants demonstrated the existence of a disputed issue of material fact regarding the causal connection between Ryan Thomas' birth defects and Provera, a drug manufactured by Upjohn, so as to preclude entry of summary judgment in Upjohn's favor; and (2) whether the trial court erred in entering summary judgment in

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[1] Dr. Zubritzsky's name has been misspelled in the caption of this appeal. The correct designation will be utilized throughout the discussion.

[2] After the entry of the orders in this case, appellants, Ryan Thomas and his parents, and Merrell-Dow Pharmaceuticals, entered into a structured settlement pursuant to which appellants would receive $50,000.00 in exchange for their discontinuance of the action against Merrell-Dow. *See* Parents' Indemnity Agreement and Joint Tortfeasors Release, at 2. The settlement agreement did not release any of the other defendants in this case. *See id.*, at 4. Consequently, appellants discontinued the action against Merrell-Dow and Merrell-Dow is no longer a party to this action. *See* Order, dated November 7, 1991 (authorizing and approving settlement). *See also* Plaintiffs' Praecipe to Settle and Discontinue Action as to Merrell-Dow Pharmaceuticals, Inc., filed November 26, 1991. Merrell-Dow thus is not a participant in this appeal.

favor of Upjohn on the basis that the warnings supplied by Upjohn to Dr. Zubritzky were adequate as a matter of law. Dr. Zubritzky raises a third question in his cross-appeal in which he suggests that summary judgment was improperly entered in favor of Upjohn on the basis that the drug taken by Mrs. Thomas may have been impure or adulterated.[3] For the reasons set forth below, we affirm all of the orders entered by the lower court.

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[3] This issue is raised in the argument portion of Dr. Zubritzky's brief. We find this particular claim to have been waived because Dr. Zubritzky failed to raise it in his statement of the questions involved. *See Dickler v. Shearson-Lehman-Hutton, Inc.*, 408 Pa. Super. 286, 290 n.1, 596 A.2d 860, 862 n.1 (1991) (concluding that an issue which was not set forth in the appellant's statement of the questions involved but which was addressed in the argument portion of the appellant's brief was not preserved for appellate review). *See also* Pa.R.A.P., Rule 2116(a), 42 Pa.C.S.A. (requiring any issue which a party wishes to be considered to be set forth in the statement of the questions and that the rule is to be considered in the highest degree mandatory, admitting of no exception).

Even were we to address the merits of this claim, Dr. Zubritzky would not be entitled to relief thereon. Dr. Zubritzky argues that if a genuine dispute of material fact exists as to whether the drug manufactured by Upjohn caused Ryan Thomas' birth defects, then it may be inferred that the drug was sold in an adulterated or impure state. Dr. Zubritzky acknowledges that there is no evidence of any type which would lend credence to his claim. *See* Dr. Zubritzky's Brief, at 19-20. Dr. Zubritzky nevertheless contends that such an inference may be deduced from the fact that Ryan Thomas was born with certain birth defects. Before an inference may be deemed sufficient to withstand entry of a summary judgment, the non-moving party must present evidence which reasonably supports the inference sought to be drawn therefrom. *See, e.g., Elder v. Nationwide Insurance Co.*, 410 Pa. Super. 290, 299, 599 A.2d 996, 1000 (1991) and *Samarin v. GAF Corporation*, 391 Pa. Super. 340, 350, 571 A.2d 398, 404 (1989), *allocatur denied*, 524 Pa. 624, 629, 574 A.2d 66, 71 (1990). Dr. Zubritzky admittedly did not submit any evidence which would support the inference which he now urges this court to make. Moreover, it may just as easily be inferred that Ryan Thomas' birth defects were the result of other non-pharmacologic factors, such as his mother's positive family history of similar birth defects, his father's Welsh-Irish ancestry

Before addressing the above issues, it is necessary to recount the relevant facts which gave rise to this appeal. Roberta and Ronald Thomas desired to have a child. Because Mrs. Thomas had an irregular or nonexistent menstrual cycle, she sought treatment from appellee and cross-appellant, Dr. Zubritzky, which commenced in the early months of 1983. Clomid, which is manufactured by Merrell-Dow Pharmaceuticals, and Provera, which is manufactured by Upjohn, were administered to Mrs. Thomas to induce ovulation and initiate or regulate her menstrual cycle. Although Mrs. Thomas completed several courses of treatment during the subsequent months, she did not become pregnant.

Despite the initial lack of success, Mrs. Thomas continued her treatment regimen of Clomid and Provera in May, 1983. Following the May treatment, Mrs. Thomas was examined by Dr. Zubritzky in July, 1983 at which time she informed him that she thought or felt herself to be pregnant. Dr. Zubritzky performed a pregnancy test which he interpreted as yielding a negative result. Accordingly, Mrs. Thomas was advised to continue taking Clomid and Provera and she did as instructed. Mrs. Thomas performed a home pregnancy test on July 20, 1983 which revealed that she was pregnant. Her pregnancy was later confirmed by a subsequent test conducted by Dr. Zubritzky. Mrs. Thomas apparently did not take any further Clomid or Provera following the diagnosis of her pregnancy by Dr. Zubritzky.

Mrs. Thomas delivered her son, Ryan, in February, 1984. Ryan was unfortunately born with a thoracic myelomeningocele,[4] which is more commonly known as

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or his mother's diet and level of health during her pregnancy. Thus, Dr. Zubritzky's inference is not the only one which may be drawn. Under these circumstances, Dr. Zubritzky's conclusory inferences are insufficient to establish a genuine issue of fact that the drug taken by Mrs. Thomas was impure or adulterated.

[4] A myelomeningocele is a sac-like protrusion of the meninges (the three layers of membrane enclosing the brain and spinal cord)

spina bifida.[5] Ryan was further diagnosed as having an Arnold-Chiari malformation[6] and hydrocephalus.[7] Surgery was performed on Ryan to correct, insofar as possible, his serious birth defects. However, Ryan has never been able to use his legs due to his condition.

Mr. and Mrs. Thomas believed that Ryan's birth defects were causally related to Mrs. Thomas' ingestion of Clomid and/or Provera during the early stages of her pregnancy. As a result, appellants initially commenced suit against Dr. Zubritzky in 1985.[8] This action was voluntarily discontinued by appellants on March 3, 1988, the day prior to jury selection.[9]

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through an opening in the wall of the spinal canal which contains nerves and cerebrospinal fluid. Schmidt's Attorneys' Dictionary of Medicine, Volume 2 at M-78 and M-207 (1988) and Volume 9 at 58 (1990 Supp.).

[5] Spina bifida is a congenital defect occurring during the embryonic development of the spine which leaves the wall of the spinal canal open at some point such that the meninges covering the spinal cord protrude therefrom and form a sac or hernia containing nerves and/or cerebrospinal fluid. Schmidt's Attorneys' Dictionary of Medicine, Volume 3 at S168-S169 (1989).

[6] A defect of this type is a developmental deformity characterized by smallness of the medulla oblongata and pons regions of the brain and the protrusion of these structures and other parts of the brain through the foramen magnum (the large opening in the back of the skull). Schmidt's Attorneys' Dictionary of Medicine, Volume 1 at A307 (1985). As part of this condition, the protruding portions of the brain and the meninges may also descend in the spinal canal. *Id.*

[7] Hydrocephalus is a condition in which an abnormal amount of cerebrospinal fluid accumulates within the cranial cavity. Schmidt's Attorneys' Dictionary of Medicine, Volume 2 at H-132 (1987).

[8] This action was docketed at GD 85-15639. Appellants were represented by different counsel in this action.

[9] According to appellants, the prior action against Dr. Zubritzky was voluntarily discontinued due to a lack of expert opinions and an inability to secure a continuation on the eve of trial. *See* Motion for Leave of Court to Execute Joint Tortfeasor Release in Minor's Claim, filed 12/3/91, at paragraph 4.

Appellants thereafter obtained new counsel who instituted the present action against Dr. Zubritzky.[10] Dr. Zubritzky joined Merrell-Dow and Upjohn as additional defendants. Both Merrell-Dow and Upjohn filed motions for summary judgment regarding the issue of causation and/or the adequacy of the warnings. These motions were granted by the trial court and summary judgment was entered thereon. *See* Orders, dated September 19, 1991. Following the entry of summary judgment, Dr. Zubritzky filed a motion for clarification of the trial court's orders. This motion was granted and an order clarifying the prior orders was entered on September 30, 1991. Appellants filed a motion for reconsideration which was denied. Dr. Zubritzky then filed a motion for summary judgment, which was granted on October 17, 1991. These timely appeals followed.[11]

As a preliminary matter, we must first ascertain whether we may exercise jurisdiction over this appeal. *See Joseph Palermo Development Corporation v. Bowers*, 388 Pa. Super. 49, 51, 564 A.2d 996, 997 (1989) (providing that this court may *sua sponte* raise a question as to its own jurisdiction). With regard to this issue, appellants assert that jurisdiction over this appeal is conferred

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[10] This action was docketed at No. GD 89-12398.

[11] Appellants initially filed an appeal from the order entered September 19, 1991, granting Upjohn's motion for summary judgment; this appeal is docketed at No. 01821 Pittsburgh 1991. Dr. Zubritzky appealed the entry of this order and the order of September 30, 1991, which clarified the prior order. Dr. Zubritzky's appeal is docketed at No. 01868 Pittsburgh 1991. Appellants also instituted an appeal from the order of clarification, entered September 30, 1991; this appeal is docketed at No. 01943 Pittsburgh 1991. Finally, appellants appealed from the order entered on October 17, 1991 which granted Dr. Zubritzky's motion for summary judgment; this appeal is docketed at No. 01942 Pittsburgh 1991. All of these appeals were consolidated for review by order of this court entered on February 7, 1992. None of the parties instituted an appeal from the September 19, 1991 order granting summary judgment in favor of Merrell-Dow.

pursuant to Pa.R.A.P., Rule 311(b), 42 Pa.C.S.A. Appellants are in error. Rule 311(b) of the Pennsylvania Rules of Appellate Procedure relates to an interlocutory appeal as of right from an order sustaining venue or personal or *in rem* jurisdiction. The orders in question here granted summary judgment and did not purport to sustain venue or jurisdiction. Accordingly, Rule 311(b) does not permit us to exercise jurisdiction over the instant appeal.

Orders granting summary judgment have been deemed final and appealable. *Sweener v. First Baptist Church of Emporium, Pennsylvania*, 516 Pa. 534, 538-539, 533 A.2d 998, 1000 (1987). This has been recognized even where the entry of a summary judgment does not terminate the litigation regarding recovery of other separate and distinct losses claimed against the same defendant or as to claims asserted against other defendants. *Id.* Since the orders granting summary judgment in favor of Dr. Zubritzky and Upjohn are final and appealable, we may exercise jurisdiction over this appeal pursuant to 42 Pa.C.S.A. § 742 of the Judicial Code.

Our standard of review in summary judgment proceedings has been enunciated by our Supreme Court as follows:

> Summary judgment is properly granted where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issues as to any material fact and that the moving party is entitled to a judgment as a matter of law." Pa.R.C.P.[, Rule] 1035(b)[, 42 Pa.C.S.A.] An entry of summary judgment may be granted only in cases where the right is clear and free from doubt. The moving party has the burden of proving the nonexistence of any genuine issue of material fact. The record must be viewed in the light most favorable to the nonmoving party, and all doubts as to the existence, of a genuine issue of material fact must be resolved against the moving party. Rule 1035 also provides

> that "[w]hen a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of his pleadings, but his response, by affidavits or as otherwise provided in this rule, must set forth *specific facts showing that there is a genuine issue for trial.* If he [or she] does not respond, summary judgment, if appropriate, shall be entered against him. Pa.R.C.P. Rule 1035(d). Therefore, where a motion for summary judgment has been made and properly supported, parties seeking to avoid the imposition of summary judgment must show by specific facts in their depositions, answers to interrogatories, admissions or affidavits that there is a genuine issue for trial.

*Marks v. Tasman*, 527 Pa. 132, 134-135, 589 A.2d 205, 206 (1991) (citations omitted) (emphasis in original). We further recognize that as an appellate court, we may "disturb the order of the trial court only where there has been an error of law or a clear abuse of discretion," *Brecher v. Cutler*, 396 Pa. Super. 211, 216, 578 A.2d 481, 483 (1990) (citation omitted). We will evaluate the decision of the lower court and the arguments of the parties in accordance with these standards.

Appellants first contend that the trial court erred in concluding that there was no disputed issue of material fact as to whether Provera was the cause of Ryan's birth defects. For support, appellants rely upon several letters from their medical experts which they believe to have amply demonstrated the existence of a dispute of material fact on the issue of causation. However, the certified record belies appellants' position.

In opposing Upjohn's motion for summary judgment, appellants' response consisted of a two-paragraph memorandum in which they baldly asserted that vast amounts of literature supported their claim that Provera caused the birth defects sustained by Ryan. Plaintiffs' Memoran-

dum in Opposition to the Upjohn Company's Motion for Summary Judgment, filed August 29, 1991. Appellants further asserted that their experts, including Dr. Goldman, agreed that Provera caused the birth defects. *Id.* Appellants attached a letter, dated January 2, 1986 from Dr. Goldman to their memorandum. *Id.*, Exhibit A. After entry of the September 19 and September 30 orders directing the entry of summary judgment in favor of Upjohn and Merrell-Dow, appellants filed a motion for reconsideration. In support of their motion, appellants attached a letter from Dr. Abramson.[12] Appellants motion for reconsideration was subsequently denied by the lower court on October 8, 1991. Following the denial of their motions, appellants thereafter filed a document that was labeled as "Plaintiffs' Response to Additional Defendants, Merrell-Dow Pharmaceuticals and the Upjohn Company's Motions for Summary Judgment" which was filed on October 10, 1991. The October 10 response indicated that appellants were including letters, attached as Exhibits A-D, to establish the existence of a genuine issue of fact as to the causation of Ryan's birth defects.[13]

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[12] Appellants explained that this letter had not been received until September 21, 1991, several days after summary judgment had been entered. Plaintiffs' Motion for Reconsideration, at paragraph 4. If appellants' expert reports had not been received as of the date of argument on the summary judgment motion, appellants could have apprised the lower court of this fact and requested a continuance until the reports were received. *See* Pa.R.C.P., Rule 1035(e), 42 Pa.C.S.A. (providing that the trial court may refuse the application for summary judgment, order a continuation to permit affidavits to be obtained or depositions to be taken or discovery to be had or may make any other such order as is just where it appears that a party opposing the motion is unable to immediately present facts which are essential to justify the opposition). Appellants did not avail themselves of this procedure with regard to Dr. Abramson's letter, however.

[13] Of these letters, Exhibit A was a copy of the January letter from Dr. Goldman which was previously attached to appellants' timely response to the summary judgment motion filed in August. Exhibits B and C were also letters from Dr. Goldman, whereas

The certified record supplied to this court indicates that appellants' attempt to defeat entry of summary judgment by introducing the additional letters from their medical experts was untimely and improper. Under similar circumstances, this court has refused to consider additional matters that were not timely or properly raised before the trial court. *See, e.g., Paparelli v. GAF Corporation*, 379 Pa. Super. 62, 67-68, 549 A.2d 597, 599 (1988) (declining to consider additional grounds asserted on appeal where the motion for summary judgment was unopposed and the appellant failed to raise these matters until after the entry of summary judgment and the denial of their motion for reconsideration); *Dillon by Dillon v. National Railroad Corporation (AMTRAK)*, 345 Pa. Super. 126, 133-134, 497 A.2d 1336, 1339 (1985) (providing that an affidavit in opposition to a motion for summary judgment must be filed within a definite time period prescribed by local rules); *Aimco Imports, Ltd. v. Industrial Valley Bank & Trust Co.*, 291 Pa. Super. 233, 237-238, 435 A.2d 884, 886 (1981) (indicating that an affidavit attached to a petition for reconsideration, filed after entry of summary judgment, could not be used to prove the existence of a genuine issue of fact as it was not filed within the requisite time period specified in Rule 1035(b)). *See also* Pa.R.C.P., Rule 1035(b), 42 Pa.C.S.A. (opposing affidavits may be filed by a non-moving or adverse party *prior* to the day of hearing). We find these authorities to be equally applicable here.

Appellants had ample opportunity to include these letters in a timely response to Upjohn's and Dr. Zubritzky's motion for summary judgment. Appellants, however, did

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**Exhibit D was the letter from Dr. Abramson which was previously appended to appellants' motion for reconsideration. We note that Exhibits B and C, the additional letters from Dr. Goldman, were written in 1985 and 1986. Although appellants apparently had Dr. Goldman's letters in their possession, appellants did not offer any explanation as to why they were not included in their August response to Upjohn's motion for summary judgment.**

not file their responses and the supporting materials until after summary judgment and their motion for reconsideration had been denied. Because the majority of the experts' letters were neither timely nor properly placed before the lower court, they cannot now be utilized to demonstrate the existence of a genuine issue of fact.[14] *See Paparelli, Dillon* and *Aimco, supra.* We will therefore only consider the timely filed letter submitted by Dr. Goldman in determining whether appellants demonstrated the existence of a genuine issue of fact.

The question of causation of Ryan's birth defects by the drug Provera is one which undisputedly falls outside the knowledge of the average layperson. *See Hamil v. Bashline*, 481 Pa. 256, 267, 392 A.2d 1280, 1285 (1978) (indicating that it is generally acknowledged that the complexities of the human body place questions as to the cause of pain or injury beyond the knowledge of the average layperson). Expert testimony is thus required to establish, with a reasonable degree of medical certainty, that Ryan's birth defects were caused by his mother's ingestion of Provera during her pregnancy. *See id.* In rendering an opinion, the expert must set forth the specific facts and the grounds relied upon which support the opinion. *See, e.g.*, Pa.R.C.P., Rule 1035(d) (requiring affidavits to set forth such facts as would be admissible in evidence) and Rule 4003.5(a)(1)(a) (providing that a party must divulge upon request by another party the identity of any expert witnesses, the facts and opinions on which the experts will testify, and the grounds for the

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[14] We reach the same conclusion with regard to appellants' response to Dr. Zubritzky's motion for summary judgment. The certified record indicates that Dr. Zubritzky's motion was granted on October 17, 1991. Appellants' response to Dr. Zubritzky's motion, to which its letters were again attached as exhibits, was not filed until October 18, 1991. Again, appellants' response must be deemed untimely and these documents cannot be considered to create a disputed issue of fact to defeat Dr. Zubritzky's motion. *See Paparelli, Dillon* and *Aimco, supra.*

experts' opinions), 42 Pa.C.S.A. We will review the evidence presented by the parties with these principles in mind.

Relevant to the issue of causation, Upjohn presented in support of its motion affidavits prepared by Dr. Arthur Haney and Dr. Harold Halvorson, both of whom indicated that it is was their opinion, within a reasonable degree of medical certainty, that Provera does not cause neural tube defects of the type sustained by Ryan Thomas. *See* Upjohn's Motion for Summary Judgment, Exhibit G, Affidavit of Dr. Haney at paragraph 8; Affidavit of Dr. Halvorson at paragraph 14. Dr. Haney supported his opinion with reference to numerous studies which concluded that neither Provera nor the class of drugs to which it belongs causes neural tube defects. Affidavit of Dr. Haney, at paragraph 8. Dr. Halvorson's affidavit was not supported with such references; instead, Dr. Halvorson's opinion appeared to be derived primarily from his experience with the drug.[15] Upjohn did not solely rely upon these affidavits but introduced other documentation in support of its position.

Specifically, Upjohn produced a copy of the proposed revisions for the Guideline Labeling Texts for Progestational Drug Products pursuant to which the FDA disclosed its proposed revision of the package insert labeling requirements. Upjohn's Motion for Summary Judgment, Exhibit J (proposed revision contained in the Federal Register; the notice indicates that the FDA intended to revise the labeling requirements due to the results of studies published since 1977, as well further analysis of previous data). The proposed revisions specifically deleted the warning that Provera caused congenital birth defects and added a warning that the drug may cause

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[15] Dr. Halvorson was employed by Upjohn as an associate director of clinical research. Affidavit of Dr. Halvorson, at paragraph 1. Dr. Halvorson's responsibilities included, *inter alia*, medical monitoring of Provera. *Id.*

genital abnormalities in infants. Upjohn also introduced a copy of the FDA committee conference at which members of the committee discussed the results of the more recent studies that had led to the revision of the labeling inserts for Provera and drugs of its class. Upjohn's Motion for Summary Judgment, Exhibit K. Finally, Upjohn submitted copies of the relevant medical articles and epidemiological and scientific studies that were relied upon or referenced by the FDA committee and Dr. Haney. Upjohn's Motion for Summary Judgment, Exhibits L-T. Although we will not recount the pertinent details of these articles and studies, we have sedulously reviewed each of them and find that they are generally supportive of Upjohn's position that Provera and drugs of the class to which it belong do not cause the neural tube defects. We also note that the articles/studies cited by Upjohn discuss in detail the prior studies previously reporting positive results of congenital birth defects and provide a critical analysis of the earlier studies which suggests that the prior reports of teratogenesis attributable to Provera or other sex hormones were unfounded.

These studies and articles in conjunction with the other documentation and affidavits supplied by Upjohn sufficiently demonstrated that there is no genuine dispute relating to the causation of Ryan's birth defects by Provera and that summary judgment may thus be appropriate. Consequently, the burden fell to appellants to establish that there remained a disputed issue of material fact for trial. Pa.R.C.P., Rule 1035(d), 42 Pa.C.S.A.; *Marks v. Tasman, supra.* Appellants' did not sustain their burden here.

As indicated above, the nature of this case requires appellants to present expert testimony or other documentation, such as a scientific study, to support their allegations of causation. *See Hamil v. Bashline, supra.* In fulfillment of this requisite, the only evidence offered by appellants consisted of their own conclusory allegations of a causal connection which they supported with the Janu-

ary 2, 1986 letter from Dr. Goldman.[16] Dr. Goldman indicated in this letter that, in his considered opinion, Ryan's thoracic myelomeningocele was a direct result of the progestins and possible estrogens, *i.e.*, Provera and Clomid, which his mother ingested. Plaintiffs' Memo-

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[16] Dr. Zubritzky questions whether this letter or any of appellants' letters, which are nothing more than unsworn statements, can properly be considered in a summary judgment proceeding. *See* Dr. Zubritzky's Brief, at 11. We agree with Dr. Zubritzky that the letters certainly do not qualify as affidavits as they do not meet any of the identified requisites. *See* Pa.R.C.P., Rule 1035(d) (providing that a supporting or opposing affidavit shall be made on personal knowledge, shall set forth such facts as would be admissible in evidence, and shall show affirmatively that the signer is competent to testify to the matters stated therein) and Rule 76 (defining affidavit as a statement in writing of facts, signed by the person making it, that either (1) is sworn to or affirmed before an officer authorized by law to administer oaths, or before a particular officer or individual designated by law as one before whom it may be taken and officially certified to in the case of an officer under his seal of office, and (2) is unsworn and contains a statement that it is made subject to the penalties of 18 Pa.C.S. § 4904 relating to unsworn falsification to authorities), 42 Pa.C.S.A.). To the extent Dr. Goldman's letter qualifies as an expert's report, it falls within the scope of permissible materials which the court may review in the context of a summary judgment motion. *See, e.g.*, Rule 1035(a) and (b) (which permit the lower court to review answers to interrogatories) and Rule 4003.5(a)(1) (which permits a party to discover, through interrogatories, the expert's opinion on a particular subject and the facts and grounds upon which the opinion is based), 42 Pa.C.S.A. Consequently, the trial court could properly consider Dr. Goldman's letter if it is considered to be a part of the answers to interrogatories. In this case, it is questionable whether appellants' letter qualify since appellants did not file the letter from Dr. Goldman or any other of their experts' letters with their answers to the opposing parties' interrogatories but merely directed the parties to the expert reports filed in the prior action between appellants and Dr. Zubritzky. *See* Rule 1035(b), *supra* (which only permits the court to consider interrogatories and other materials which are on file). In view of our disposition, we will not definitively resolve this matter and we will assume that Dr. Goldman's letter was properly considered as part of the answers to the interrogatories.

randum in Opposition to the Upjohn Company's Motion for Summary Judgment, Exhibit A, at 2. Dr. Goldman further stated that it was his considered opinion that Provera and possibly Clomid caused Ryan's neural tube defects. *Id.*

Dr. Goldman's letter is inadequate because it merely sets forth his medical conclusions on the question of causation. What is completely lacking, however, is the specific factual basis and grounds upon which his conclusions rest. Dr. Goldman's letter also did not attempt to respond to the matters raised by Upjohn in that he did not contradict or explain the findings of the studies cited by Upjohn. Dr. Goldman likewise did not discuss the effect which other factors, such as Mrs. Thomas' positive family history of spina bifida or Mr. Thomas' Welsh-Irish ancestry may have had in contributing to Ryan's birth defects.[17] Instead, Dr. Goldman's opinion appeared to be

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[17] In support of its motion for summary judgment, Merrell-Dow relied, in part, upon an affidavit from Dr. James Mills and a letter from Dr. Mark Steele to appellants. Merrell-Dow's Motion for Summary Judgment, Exhibit B (Affidavit of Dr. Mills, a pediatric epidemiologist) and Exhibit C (letter, dated December 22, 1987, from Dr. Steele to Mr. and Mrs. Thomas). In his expert capacity as a pediatric epidemiologist, Dr. Mills reviewed medical records pertaining to Mrs. Thomas' maternal aunt, who had died in infancy of spina bifida. Affidavit of Dr. Mills, at paragraph 12. Dr. Mills further added that Mr. Thomas was of Welsh-Irish ancestry and that these particular ethnic groups exhibit a higher rate of neural tube defects than other ethnic groups. *Id.* Dr. Mills concluded that Ryan's birth defects were not caused by his mother's ingestion of Clomid. *Id.*, at paragraph 13. Similar conclusions were reached by Dr. Steele, a geneticist with whom Mr. and Mrs. Thomas consulted regarding their risk or probability of having another child with birth defects. In his letter, Dr. Steele indicated that Ryan's birth defects were not caused by the Clomid and Provera taken by Mrs. Thomas, but was rather the result of a variety of factors, including Mrs. Thomas' family history of spina bifida and Mr. Thomas' Welsh-Irish ancestry. Although the propriety of the summary judgment entered in Merrell-Dow's favor is not currently before this court, we note that Dr. Zubritzky relied upon Dr. Steele's letter as well as other materials submitted by both Merrell-Dow

based solely on the fact that Mrs. Thomas had ingested the drugs during the early part of her pregnancy. The mere fact that she took the drug, without more, does not establish causation. Because appellants offered nothing more than the conclusory opinions of their expert which were unsupported by any specific facts or other adequate grounds, we conclude that they failed to establish a disputed issue of fact regarding Provera as the cause of Ryan's birth defects.[18] *See Brecher v. Cutler*, 396 Pa. Super. at 216, 578 A.2d at 483 (citation omitted) (providing that bold unsupported assertions of conclusory accusations cannot create genuine issues of material fact to defeat the entry of summary judgment). *See also Ambrosini v. Labarrague*, 966 F.2d 1464, 1470 (D.C. Cir. 1992) (indicating that summary judgment may be

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and Upjohn in his own motion and in his responses to Merrell-Dow's and Upjohn's motions for summary judgment. These materials may therefore be appropriately considered with regard to this appeal.

[18] Although we express no opinion as to whether consideration of the additional letters may have precluded entry of summary judgment, we note that one of the experts expressed no opinion as to the issue of causation and two others failed to express an opinion in terms of the requisite degree of medical certainty or with sufficient definiteness. *See Pirches v. General Accident Insurance Co.*, 354 Pa. Super. 303, 308-310, 511 A.2d 1349, 1352-1353 (1986) (discussing requirements of expert testimony and indicating that an expert does not meet the standard if he or she testifies that the alleged cause "possibly" or "could have" led to the result, that it "could very properly account" for the result" or event that it was "very highly probable" that it caused the result). While the two remaining letters do not suffer from these defects, they appear to rely on the older studies which have been repudiated or at least seriously called into doubt by the more recent reports. We further note that appellants have relied upon many of the same experts who were to be used in the first action against Dr. Zubritzky, which was allegedly discontinued because of the experts' refusal to testify. In view of the defects in the experts' opinions, their reliance on studies whose value is now questionable, and the experts' own actions, the letters would not appear to have defeated entry of summary judgment even had they been timely presented to the lower court.

proper where the affidavits of the medical experts are insufficient to create a genuine issue of material fact). Under these circumstances, the trial court properly entered summary judgment in favor of Upjohn and Dr. Zubritzky.[19]

Appellants' second issue relates to the trial court's determination that summary judgment in favor of Upjohn was appropriate because the warnings on the package insert were adequate as a matter of law. The extent of a drug manufacturer's liability in the context of a failure to adequately warn of the risks associated with usage of the drug has been defined by our Supreme Court as follows:

> assuming proper preparation and warning, a manufacturer of drugs is not strictly liable for [the] unfortunate consequences attending the use of otherwise useful and desirable products which are attended with a known but apparently reasonable risk. Rather, such a manufacturer is liable only if [it] fails to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous. . . . [A]lso[,] . . . a drug manufacturer can be held to have breached [its] duty of reasonable care by promoting its product in such a way as to nullify printed warnings.

*Baldino v. Castagna*, 505 Pa. 239, 244, 478 A.2d 807, 810 (1984), *citing Incollingo v. Ewing*, 444 Pa. 263, 288, 282 A.2d 206, 219-220 (1971). In addition, where the drugs in question are available by prescription only, the warning required is not to the general public or to the patient, but to the prescribing doctor. *Coyle by Coyle v. Richardson-Merrell, Inc.*, 526 Pa. 208, 213, 584 A.2d

[19] Our discussion of Upjohn's motion for summary judgment is equally applicable to Dr. Zubritzky because his liability to appellants is dependent upon the issue of causation in that he cannot be held liable if Ryan's birth defects were not caused by his exposure to Provera.

1383, 1385 (1991). *Accord Baldino v. Castagna*, 505 Pa. at 247, 478 A.2d at 812; *Incollingo v. Ewing*, 444 Pa. at 288, 282 A.2d at 220. We will evaluate the adequacy of the warning in accordance with these decisions.

It is not disputed that Provera was available only by prescription. Accordingly, the warning in this case was given to the physician and not Mrs. Thomas. The warning in effect at the time Mrs. Thomas took Provera appeared as follows:

> THE USE OF PROGESTATIONAL AGENTS DURING THE FIRST FOUR MONTHS OF PREGNANCY IS NOT RECOMMENDED
>
> Progestational agents have been used beginning with the first trimester of pregnancy in an attempt to prevent habitual abortion or treat threatened abortion. There is no adequate evidence that such use is effective and there is evidence of potential harm to the fetus when such drugs are given during the first four months of pregnancy. Furthermore, in the vast majority of women, the cause of abortion is a defective ovum, which progestational agents could not be expected to influence. In addition the use of progestational agents, with their uterine-relaxant properties, in patients with fertilized defective ova may cause a delay in spontaneous abortion. Therefore, the use of such drugs during the first four months of pregnancy is not recommended.
>
> Several reports suggest an association between intrauterine exposure to female sex hormones and congenital anomalies including congenital heart defects and limb reduction defects. One study estimated a 4.7-fold increased risk of limb reduction defects in infants exposed in utero to sex hormones (oral contraceptives, hormone withdrawal tests for pregnancy or attempted treatment for threatened abortion). Some of these exposures were very short

and involved only a few days of treatment. The data suggest that the risk of limb reduction defects in exposed fetuses is somewhat less than 1 in 1000.

If the patient is exposed to PROVERA Tablets (medroxyprogesterone acetate) during the first four months of pregnancy or if she becomes pregnant while taking this drug, she should be apprised of the potential risks to the fetus.

Upjohn's Motion for Summary Judgment, Exhibit I (Package Insert) (references to footnotes omitted).

Appellants first contend that the trial court erred in determining the adequacy of the warning as a matter of law because such matters raise factual questions which can only be resolved by the trier-of-fact. Notwithstanding appellants' arguments to the contrary, the adequacy of a drug manufacturer's warning may be determined by the courts as a matter of law, absent the existence of facts demonstrating that the warning was inadequate.[20] *Brecher v. Cutler*, 396 Pa. Super. at 219, 578 A.2d at 485 (affirming the trial court's entry of summary judgment in favor of the manufacturer on the basis that the warning was adequate where the physician's deposition testimony indicated that he had read the warning and was aware of the side effects and risks associated with usage of the product).

Appellants and Dr. Zubritzky next argue that the warning was inadequate because it only "recommended" that the drug not be used during the first four months of

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[20] Our conclusions are not inconsistent with our Supreme Court's discussion in *Incollingo v. Ewing*. In that case, the Supreme Court concluded that even if the package warning was deemed adequate as a matter of law, a factual question remained as to whether the efforts of the drug salesmen or "detail men" had nullified the warnings. There is no evidence that Upjohn's detail men over-promoted the product in this case or that their conduct nullified the warnings nor have any other disputed issues of fact relating to the adequacy of the warning been presented.

pregnancy. Appellants thus suggest that a stronger requirement, *i.e.*, "avoid at all costs any possibility of exposure during pregnancy" was required.[21] *See* Appellants' Brief, at 6. Appellants and Dr. Zubritzky also challenge the adequacy of the warning on the basis that it failed to identify the precise nature of the risk, *i.e.*, that fetal exposure could cause the particular type of birth defects from which Ryan suffers. We disagree.

The warning provided by Upjohn clearly advised the prescribing physician that fetal exposure may result in congenital anomalies, including heart and limb reduction defects. This language was sufficiently broad enough to cover any and all possible fetal malformations.[22] We therefore reject appellants' and Dr. Zubritzky's suggestion that this all-inclusive warning was inadequate because it failed to specifically identify neural tube defects as a potential risk.

The warning is likewise not rendered inadequate merely because it recommended that Provera should not be taken during the early stages of pregnancy. The recommendation referred to prior usage of the product to treat abortion or as a pregnancy test. The warning thus advised physicians that continued usage of Provera for these situations was not recommended because it was ineffective for these purposes and because it could possibly harm the developing fetus. The warning further apprised physicians of the relative risk of defect to a fetus that had been

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[21] Dr. Zubritzky's arguments are similar to those presented by appellants. Our discussion of appellants' claims will therefore be equally applicable to Dr. Zubritzky.

[22] In fact, Upjohn's warning contained a reference to the Gal study cited by Dr. Goldman in his 1985 letter. According to Dr. Goldman, Gal detected a causal connection between neural tube defects and fetal exposure to sex hormones. The references to Gal and other studies thus suggests that Upjohn's warning was intended to cover a broad spectrum of congenital defects rather than being limited to only include heart or limb reduction anomalies as now argued by appellants.

exposed to the drug. Neither appellants nor Dr. Zubritzky presented any evidence demonstrating that the risk of defect was substantially higher than that reported in the warning nor have they presented anything else which would justify their position that the warning should have instructed physicians to take every known precaution to avoid exposing the fetus to the drug.

More importantly, Dr. Zubritzky indicated that he was familiar with the information contained in the warnings as well as in the medical literature and that he followed the warning instructions by testing Mrs. Thomas for pregnancy before instructing her to continue with her treatment regimen. *See* Upjohn's Motion for Summary Judgment, Exhibit F (excerpt of Dr. Zubritzky's deposition testimony in which he indicates that he was familiar with the package insert). *See also* Dr. Zubritzky's Brief, at 18 (in which he indicates that he did not use the product in contravention of the warning in that he did not prescribe the drug as a pregnancy test, or to prevent abortion and that he tested Mrs. Thomas for pregnancy before continuing further treatment). Dr. Zubritzky's own admissions, in the absence of any other evidence, compel us to conclude that the warnings were adequate. Consequently, Upjohn was entitled to summary judgment on this basis.

Orders affirmed.

**APPENDIX D**

IN THE COURT OF COMMON PLEAS
OF ALLEGHENY COUNTY, PENNSYLVANIA

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CIVIL DIVISION

GD 89-12398

RYAN THOMAS, a minor by ROBERTA THOMAS and RONALD C. THOMAS, JR., his natural parents and guardians,

*Plaintiffs,*

vs.

PAUL D. ZUBRITZKY,

*Defendant,*

vs.

THE UPJOHN COMPANY and MERRELL DOW PHARMACEUTICALS INC.

*Additional Defendants.*

---

ORDER OF COURT

AND NOW, to-wit, this 19th day of September, 1991, upon consideration of the motion for summary judgment filed by Additional Defendant Merrell Dow Pharmaceuticals, Inc., it is hereby ORDERED that said motion is granted.

BY THE COURT:

/s/ McLean, J.

IN THE COURT OF COMMON PLEAS
OF ALLEGHENY COUNTY, PENNSYLVANIA

---

CIVIL DIVISION

GD 89-12398

RYAN THOMAS, a minor by ROBERTA THOMAS and RONALD C. THOMAS, JR., his natural parents and guardians,

*Plaintiffs,*

vs.

PAUL D. ZUBRITZKY,

*Defendant,*

vs.

THE UPJOHN COMPANY and MERRELL DOW PHARMACEUTICALS INC.

*Additional Defendants.*

---

ORDER OF COURT

AND NOW, to-wit, this 19th day of September, 1991, upon consideration of the motion for summary judgment filed by Additional Defendant the Upjohn Company, the original defendant consenting to the motion on the grounds of causation, and Upjohn having advanced its package warnings as a defense, it is hereby ORDERED that said motion is granted.

BY THE COURT:

/s/ McLean, J.

## ORDER

And now, this 30th day of September, 1991, this court's Order of September 19, 1991 is hereby clarified as follows:

Summary judgment is granted in favor of Additional Defendant, The Upjohn Company, and against plaintiff and original defendant on the ground that there is no genuine issue of fact material to the issue of causation and the court finds as a matter of law that the drug Provera was not a cause in fact of the birth defects and personal injuries for which recovery is sought. Further, as a separate and independent ground, summary judgment is granted to The Upjohn Company and against plaintiff and original defendant, as the court finds that the Upjohn Company provided a warning which was adequate as a matter of law and that there is no issue of material fact as to any defect in the product.

BY THE COURT

/s/ McLean, J.

## ORDER OF COURT

And now, this 17th day of October, 1991, summary judgment is hereby entered in favor of original defendant and against plaintiff, the court finding, consistent with its Orders of September 19, 1991, that there is no genuine issue of material fact regarding the question of causation and that original defendant is entitled to summary judgment as a matter of law and for the additional reason that plaintiff is precluded by the judgments entered September 19, 1991 from further litigating the question of causation.

BY THE COURT:

/s/ McLean, J.

## APPENDIX E

IN THE COURT OF COMMON PLEAS
OF ALLEGHENY COUNTY, PENNSYLVANIA

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CIVIL DIVISION

GD 89-12398

RYAN THOMAS, a minor, by ROBERTA THOMAS and RONALD C. THOMAS, JR., his natural parents and guardians,

*Plaintiffs,*

vs.

PAUL D. ZUBRITZKY,

*Defendant,*

vs.

THE UPJOHN COMPANY and MERRELL DOW PHARMACEUTICALS INC.,

*Additional Defendants.*

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MEMORANDUM OPINION

SUMMARY JUDGMENT
MEDICAL MALPRACTICE

Filed by the Honorable James H. McLean

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IN THE COURT OF COMMON PLEAS
OF ALLEGHENY COUNTY, PENNSYLVANIA

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CIVIL DIVISION

GD 89-12398

RYAN THOMAS, a minor, by ROBERTA THOMAS and RONALD C. THOMAS, JR., his natural parents and guardians,

*Plaintiffs,*

vs.

PAUL D. ZUBRITZKY,

*Defendant,*

vs.

THE UPJOHN COMPANY and MERRELL DOW PHARMACEUTICALS INC.,

*Additional Defendants.*

McLEAN, J. January 14, 1992

MEMORANDUM OPINION

Roberta Thomas was treated by the Defendant Paul D. Zubritzky for infertility. Dr. Zubritsky prescribed the drugs Provera and Clomid in an effort to induce and to regulate Ms. Thomas' menstrual periods. Ms. Thomas took these drugs unaware that she was already pregnant. On February 26, 1984, Ryan Thomas was born suffering from the neural tube defects of spina bifida and hydrocyshaly.

Ryan's parents brought this lawsuit on his behalf against Dr. Zubritsky, who then joined The Upjohn Company, manufacturer of Provera, and Merrell Dow Pharmaceuticals, Inc., manufacturer of Clomid. On September 3, 1991, both additional defendants moved for

summary judgment and these motions were granted on September 19, 1991.* On October 17, 1991, Dr. Zubritsky moved for summary judgment, which was granted that same day. An appeal by Plaintiff, and cross appeal by Zubritzky as to Upjohn only, ensued.

Both additional defendants moved for summary judgment primarily on the issue of causation, contending that, as a matter of settled scientific fact, their drugs could not have caused Ryan's birth defects. The evidence marshalled in support of these contentions was substantial if not overwhelming. Merrell Dow presented the affidavits of two highly regarded experts, one of whom has authored a study in *The Lancet* on this subject, to the effect there is no correlation between Clomid and neural tube defects. The Thomases were also evaluated by the genetics department of Magee Women's Hospital, who concluded that Ryan's problems were hereditary, due to his father's Welsh/Irish descent and a history of spina bifida in his mother's family.

Upjohn likewise contended that there was no link between Provera and neural tube defects. In fact before 1977 Provera was used both as a pregnancy test and as a treatment for threatened miscarriage. Based on an early study suggesting a possible correlation between synthetic progesterones and fetal limb reductions and heart defects, the FDA once required that Provera carry a cautionary statement concerning its use during pregnancy. Such warnings were provided by Upjohn at the time Dr. Zubritsky prescribed the drug for Mrs. Thomas. However, in 1989 the FDA eliminated the requirement of warnings, having concluded that sex hormones do not cause birth defects. Provera has never been associated with neural tube defects.

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*** The Upjohn order was later amended on September 30, 1991, to reflect more fully the grounds upon which the motion was granted.**

In summation, both additional defendants introduced ample evidence of a settled consensus in the scientific community that Clomid and Provera do not cause neural tube defects. Dr. Zubritsky himself concurred with their position on the issue of causation, challenging only the issue of the adequacy of Upjohn's warnings. In response to these positions Plaintiff simply contends that the question of causation presents a material question of fact such as to preclude the entry of summary judgment. However, the phrase "material question of fact" is not a shibboleth whose mere utterance will preclude summary judgment.

Unfortunately the evidence proffered by Plaintiff to refute the defense motions falls far short of establishing a genuine issue of material fact. This proof consists of a series of letters from physicians flatly stating a correlation between these drugs and neural tube defects and therefore attributing Ryan's problems to that source. On the whole these conclusions are highly conjectural, and they are plainly maverick in nature. Also, none of Plaintiff's experts address the issue of heredity in Ryan's case.

The paucity of Plaintiff's proof contrasted with the highly credible and substantial evidence offered by the Defendants indicates that there is no genuine issue of material fact as to causation and that to allow this case to proceed to trial by jury would be to risk a verdict based on sympathy and conjecture. The orders (copies attached) entering summary judgment in favor of all defendants were therefore proper.

## APPENDIX F

### EXHIBIT "A"

ILLINOIS COLLEGE OF
MEDICINE AT CHICAGO

Center for Craniofacial Anomalies
408 South Wood Street
Box 6998, Chicago, Illinois 60880
(312) 996-7548

January 2, 1986

James G. Gordon, Esquire
220 Grant Street
Pittsburgh, PA 15219

RE: Ryan C. Thomas
Date of Birth: February 26, 1984

Dear Mr. Gordon:

Per your request, I have set forth my opinions reached as a result of an evaluation of events surrounding the birth of Ryan C. Thomas, born on February 26, 1984. In doing so, I have reviewed the following documents and materials: (a) the hospital records from Ohio Valley General Hospital pertaining to the birth of Ryan Thomas; (b) the laboratory records from Ohio Valley Hospital for blood pregnancy tests; (c) the in-patient records of Ryan Thomas from Children's Hospital of Pittsburgh from February 26, 1984 through March 30, 1984; (d) a receipt from prescriptions filled by Dr. Zubritsky for Roberta Thomas for the period from January 1, 1983 through December 31, 1983; (e) the 1939 records from The Valley Hospital and (f) a case history.

SUMMARY OF MEDICAL EVENTS:

Roberta Thomas, a twenty-three (23) years old female, had a history of irregular menstrual periods for which she had been prescribed Provera, 10 mg for ten (10) days and Clomid, 50 mg for ten (10) days, 5 to 10 days after menstrual period. Clomid is a drug used to induce ovulation. This regimen was prescribed for three cycles by history, she would get blood tests and call Dr. Zubritsky's office, if the tests were negative then she would begin the Provera cycle again. The monthly blood tests were pregnancy tests. On May 14, 1983, Mrs. Thomas was told that the blood pregnancy test was negative and that she could begin the Provera, which she did. On May 21 she began her menstrual period apparently while still taking the Provera. She began taking Clomid 150 mg per day for five (5) days starting on May 25, 1983. On July 5, 1983 she was seen by Dr. Zubritsky, a urine pregnancy test was performed in his office and the report that the test was "positive then turned negative." Mrs. Thomas took the Provera July 5, 1983 through July 14, 1983. On July 18, 1983 she began spotting, the next day she obtained a home pregnancy test and found that it was positive. She was examined by Dr. Zubritsky on July 28, 1983 and was thought to be about eight (8) weeks size on pelvic examination. On October 5, 1983 she had a sonogram which gave the gestational age of eighteen (18) weeks, or a conception date on or about June 2, 1983. This was consistent with the size estimated on July 28, 1983 and also with the estimated date of conception. Size and date were consistent throughout the pregnancy. A second sonogram was performed on January 17, 1984 for fetal presentation and biparietal diameter (BPD). The report indicated that the BPD was 88mm equivalent to thirty-six (36) weeks. It also stated that there were "changes consistent with dilated ventricles." No other mention of survey of fetal anatomy is mentioned other than fetal motion and cardiac activity being seen.

On February 26, 1984 Mrs. Thomas was admitted to Ohio Valley General Hospital in active labor and delivered Ryan. He weighed 6 lbs. 11 oz., and had APGAR scores listed as 9 and 10 at 1 in five minutes, respectively. He was noted to have a myelomeningocele in the thoracolumbar area (spina bifida). He was transferred to Children's Hospital in Pittsburgh, Pennsylvania, on February 26, 1984. He was found to have no movement or sensation to pain in his legs or lower body. Surgical repair of the open meningomyelocele and spinal surgery and plastic repair was performed on the same day, February 26, 1984. He was found to develop hydrocephalas, originally controlled by ventricular taps, but then he had a ventricular shunt placed. CT scans of his head had shown concave petrous bones in a small posteria fossa which was consistent with a Chiari type II malformation. The CT of February 26, 1984 suggested subependymal and cortical hemorrhage in both occipital lobes. Ryan is unable to move his legs and will never have that function.

It is my considered opinion that the thoraco-myelomeningocele was a direct result of the progrestins and possible estrogens to which the fetus was exposed in the earliest stages of Roberta Thomas' pregnancy. Provera is a progestin and Clomid is an estrogen.

In conclusion, it is my considered opinion that the fetal exposure to Provera and possibly Clomid caused the neural tube defect from which this child suffers.

If you have any further questions regarding the above, please do not hesitate to call me.

Sincerely,

/s/ Allen S. Goldman, M.D.
ALLEN S. GOLDMAN, M.D.
Director
Center for Craniofacial Anomalies

ASG:pl

EXHIBIT "B"

[SEAL]

FOUNDED 1855

THE CHILDREN'S HOSPITAL OF PHILADELPHIA
34th Street and Civic Center Boulevard • Philadelphia, Pa. 19104 • (215) 596-9100

November 13, 1985

Mr. James G. Gordon
Wymard, Dunn & Gordon
Attorneys at Law
220 Grant Street
Pittsburgh, PA 15219

In re: Roberta M. Thomas vs. Paul M. Zubritsky, M.D.

Dear Mr. Gordon:

I have carefully reviewed all the materials which you have sent me and have done a preliminary literature search concern the possibility that the child's multiple birth defects were due to the combination of the mother's exposure to clomid and Provera.

Concerning the thoraco-myelomeningocle one of the earliest reports in which the malformations of other organs was attributed to the use of exogenous progestins was that of Uhlig (1). He observed three deformed infants with central nervous system defects (like the present case), club foot, and limb reduction defects. After the original observation of Gal (2) showing an excess of neural tube defects with hormone pregnancy tests exposure (combination of progestin and estrogen as in the present case) was criticized by Laurence (3,4) and Sever (5), Gal and colleagues reexamined their previously reported data and concluded that even when such factors as maternal age

and reproductive history were controlled, there was a significant association between neural tube occurrence and exposure to sex hormones used in pregnancy tests (6). Moreover, Roussel, 1969 (unpublished observations) had a significant excess of central nervous system anomalies in progestin and estrogen exposed offspring. Similar finding were reported by Greenberg (7,8), Kazan and Andrews (9), Torfs (10), and Bracken (11). An animal model has been reported for CNS defects produced by norethynodrel (12) and lynestrenol (13). The incidence of CNS malformations has fallen in the United States (14), Ireland (15), and England (16) during the years after these progestins were reported to be teratogenic.

Thus, there is evidence of association of CNS defects with exposure in early pregnancy to both progestins and estrogens which the present case is an example, Provera being a progestin and Clomid being a estrogen.

There are several reports however, indicating that there is little to no teratogenic risk (see enclosed copy). In my opinion, the weight of the evidence is in favor of the teratogenicity of the exposure to these two agents and the time of exposure is in the right period.

Sincerely,

/s/ Allen S. Goldman, M.D.
ALLEN S. GOLDMAN, M.D.
Research Professor of
Pediatrics and Teratologist
Section of Teratology,
Division of Child
Development and
Rehabilitation

ASG:bs

cc: Association of Consulting Toxicologists

EXHIBIT "C"

THE UNIVERSITY OF ILLINOIS
COLLEGE OF MEDCINE AT CHICAGO

Center for Craniofacial Anomalies (M/C 588)
808 South Wood Street
Chicago, Illinois 60612
(312) 996-6979

Allen S. Goldman, M.D.
Director
Professor of Pediatrics,
Craniofacial Anomalies,
and Genetics

16 Jun 86

Mr. James G. Gordon
Attorney at Law
Law Offices of Wymard, Dunn & Gordon
220 Grant Street
Pittsburgh, PA 15219

Dear Mr. Gordon:

I am writing to supplement my earlier report dated January 2, 1986, as a result of additional information and input received from you.

You have provided me with the following pertinent dates:

| | |
|---|---|
| February, 1983 | Roberta begins Provera-Clomid therapy. |
| May 14, 1983 | Blood test at hospital negative for pregnancy. |
| May 21, 1983 | Last period began. (Roberta's periods lasted 2 days, rarely 3 days, never lasted 4 days). |
| May 25, 1983 | Began taking Clomid for 5 days, 3 tablets per day. 50 mg. (150 mg. daily) (25th, 26th, 27th, 28th and 29th). |

| | |
|---|---|
| July 5, 1983 | Begins taking Provera for 10 days (July 5-July 14) |
| February 26, 1984 | Ryan Thomas born on due date, as projected by Dr. Zubritzky. |

Based upon the above, it is my opinion, on the basis of a reasonable degree of medical certainty, that the early conceptus was exposed to Clomid.

The fact that Mrs. Robert M. Thomas was given 150mg/day instead of 100 mg/day of Clomid for five (5) days would result in a higher concentration of this drug in her system for a longer period of time.

Thus, it is likely that the defects occurring in Ryan can be attributed to the increased risk of spina bifida due to exposure to these drugs.

If you have any further questions regarding the above, please do not hesitate to contact me.

Sincerely yours,

/s/ Allen S. Goldman, M.D.
ALLEN S. GOLDMAN, M.D.
Director
Center for Craniofacial Anomalies

EXHIBIT "D"

David Abramson, M.D., F.A.A.P., A.C.E.P.

EMERGENCY MEDICINE PEDIATRICS AND
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Sept. 8, 1991
Steven Savor, Jr., Esq.
LEWIS & STOCKEY
1040 5th Ave.
Pittsburgh, PA 15219

Re: Thomas, Ryan

Dear Steven Savor, Jr., Esq.:

I have now had a chance to carefully review all of the records that you forwarded for the pregancy, birth, pediatric care, and follow-up care of Ryan Thomas. I have also reviewed the appropriate literature but I have not had the opportunity to examine this child. Based on my examination, I have the following understanding and hold the following opinions in this case.

After apparent difficulty in conceiving, Ryan's mother was placed on dual, pharmacologic therapy to induce ovulation-conception. Progestigens are specifically contraindicated after conception has taken place.

The pregnancy in question was not diagnosed until after Provera had been given during the first trimester. Because compliance with the admonition against Provera's use in pregnancy has been so good, too few women have been exposed in recent times to draw definitive conclusions about the type of malformations that may result. Certainly, dymorphogenesis is known to occur in the presence of a host of non-physiologic fetal environments.

It is abundantly clear that a significant increase in the likelihood of neural tube defects could go undetected with current exposure rates for nearly a century.

It is my very strong opinion that standard avoidance of fetal Provera exposure would probably have prevented this child's Arnold-Chiari II malformation.

Please feel free to call me if you need to discuss this in greater detail.

Very truly yours,

/s/ David Abramson, M.D.
DAVID ABRAMSON, M.D.